Philips Medical Systems

NEWSLETTER **Service**

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Information for : FSE Manager Specialist

FCO for 3° - PBL

For USA only

Applies to the following systems shipped by GXR between 1996 and September 2005:

BuckyDiagnost
DigitalDiagnost
EasyDiagnost
EasyDiagnost Eleva
OmniDiagnost Eleva
MultiDiagnost Eleva

Symptom: Due to approval reason of Positive Beam Limiting (PBL) function each affected x-ray system has to be modified on site.

Announcement: The following FCOs 'Action for Performance' will be introduced soon:

FCO 70400019	±3°- PBL BuckyDiagnost
FCO 71200019	±3°- PBL DigitalDiagnost
FCO 70600022	±3°- PBL EasyDiagnost Eleva
FCO 70600023	±3°- PBL EasyDiagnost Classic
FCO 70800069	±3°- PBL Omni / Multi Diagnost Eleva

Period: within 5 years after the data of the customer notification letter
Installation of the PBL-modification kit is to be executed at the point when an affected system requires an X-Ray tube exchange (retrofit on failure of the tube).

Action plan:

1. The respective customers will be informed via Customer Notification Letter (see attachment). The letter includes a questionnaire to be sent back and a label to be fixed to the control handle.
2. Do not order precautionary!
3. The FCO will only be installed on request of the customer. Each customer triggers the upgrade of his system.

Availability:

FCO kits can be ordered earliest 6 weeks after Customer Notification Letter.

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Appendix:

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PHILIPS

Philips Medical Systems

Electronic Product Radiation Warning
via Certified Mail - Return Receipt Requested

July 9, 2007

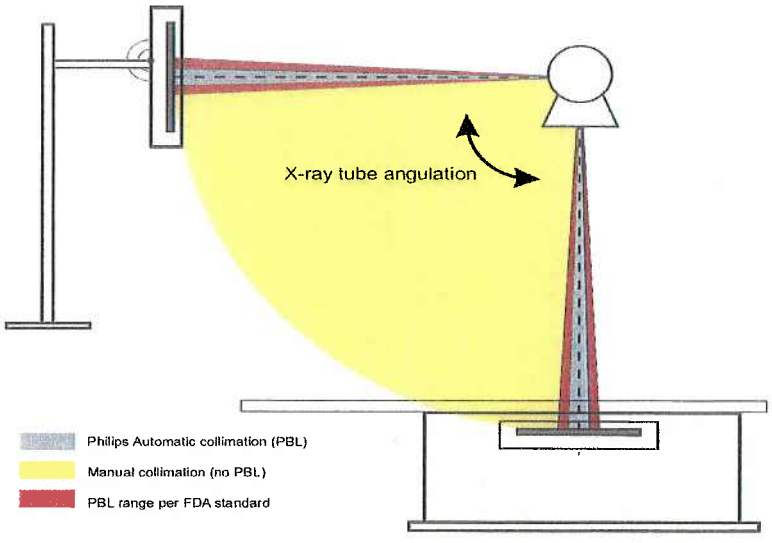
RE: Notification of Positive Beam Limitation (PBL) Operation in Philips General Purpose X-ray Systems (BuckyDiagnost, DigitalDiagnost, EasyDiagnost, EasyDiagnost Eleva, OmniDiagnost Eleva, MultiDiagnost Eleva systems with the automatic collimation option, manufactured from 1996 through September 2005). FCO 70400019

Dear Director of Radiology or Manager of Biomedical Engineering:

Philips is notifying you that some of the above listed general X-ray systems do not automatically collimate over the full ± 3 degree range for PBL as specified in the FDA X-ray Performance Standard. This letter is to provide you with additional information about the system design in order for operators to appropriately use the system and announces a system modification kit that corrects the non-compliance. This system modification should be installed the next time an x-ray tube replacement is required.

Positive Beam Limitation (PBL) is an automatic collimator sizing function required on all general purpose X-ray systems that allow operation in both manual and automatic mode. Automatic collimator sizing is when the collimator automatically sizes the x-ray field to the film size in the cassette holder. The FDA standard requires that automatic collimator sizing be applied for the full ± 3 degree range when operating at 0 or 90 degrees or when the collimator is perpendicular to the X-ray field. Manual collimator sizing may then be used for any rotational angle between 3 and 87 degrees. These Philips X-ray systems have tighter alignment tolerances and detents to maintain the collimator perpendicular; consequently PBL operates within a narrower range than the specified ±3 degrees. In affected Philips units, PBL typically functions up to an angle of ±1.5 degrees off perpendicular rather than the required full ±3 degree range. These systems nonetheless clearly alert the user when PBL is not active.

Figure 1 demonstrates PBL operation on Philips general purpose X-ray systems.



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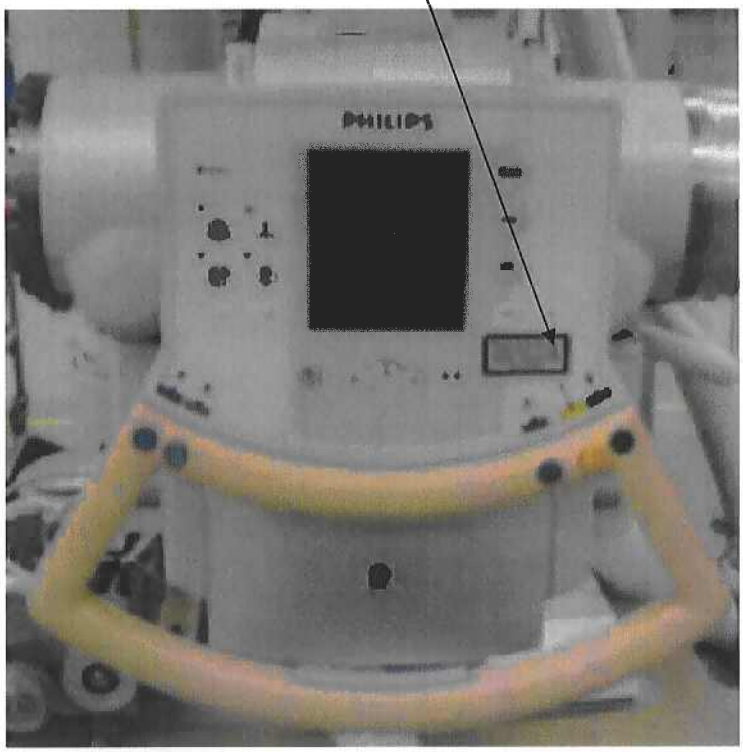
www.philips.com

When the collimator is angled between 1.5 and 3 degrees, the system as originally assembled at your facility currently displays to the operator that the system is in manual mode, and that radiation exposure can be initiated. This is contrary to the Conditions for PBL operation stated in the FDA X-ray Performance Standard, which requires that, for diagnostic x-ray systems equipped with PBL collimation, the PBL system will be active within this angular range, as indicated by the letter "A" on the collimator operating mode display at the operator's position. If the collimator is angled between 1.5 and 3 degrees and this is the intended tube angle, the operator must follow the normal process of manually setting the collimator to the film size in the cassette holder. As is always the case in manual mode, if the operator's sizing is not correct, an additional X-ray exposure may be required to obtain the desired image. If the operator did not intend to angle the collimator, they can adjust it and the system will confirm that it is in automatic mode.

To further emphasize to operators the importance of ensuring that the system is in the intended mode, a caution label is enclosed with this letter. Please attach this label to the collimator as shown in Figure 2.

Figure 2: Suggested Label location



When operating the system please ensure that any X-ray exposure is properly sized.

For exposures perpendicular to the X-ray beam (system is in Automatic mode)

1) The X-ray source is set in the detents for exact horizontal and vertical perpendicular beam angle
2) Indication light is "ON" when beam is perpendicular to the receiver
3) "A" is displayed on collimator indicating Automatic collimation mode
4) Numerical values for SID are displayed
5) The collimator light field is used to check the X-ray field for placement of and size of field
6) Centers are aligned to center the X-ray beam on the film cassette

For angled exposures or exposures not perpendicular to the X-ray beam (system is in Manual mode)

1) The X-ray source is set to the desired angle
2) Indication light is "OFF"
3) "M" is displayed on collimator indicating manual collimation mode
4) SID value is displayed as "???"
5) The collimator light field is used to display and adjust X-ray field for placement and size of field
6) Centers are aligned to center the X-ray beam on the film cassette

The system modification for PBL will be installed at no cost to you. Regardless of your service organization, please notify your Philips Field Service Representative when your system requires an X-ray tube exchange so the PBL modification can be scheduled and completed at that time. The phone number to schedule this modification is 1-800-722-9377 menu 5, 2.

Should you prefer to have the kit installed by your own service organization, then Philips will provide you with the correction kit and the installation instructions free of charge upon your request.

Please consult the attached information to help determine if your system is affected by the planned PBL modification. Should the system in question be no longer in service or have been sold to another institution, or should you intend to take it out of service or sell it, please contact Philips Medical Systems at 1-800-722-9377 menu 5, 2 with this information.

Please share this information with all X-ray system operators and insert this letter in your Instructions for Use Manual. Please contact me if you have additional questions regarding this notification. I may be reached at 425-487-7665.

Sincerely,

Sarah Baxter

Sarah Baxter
Director, Regulatory Affairs
Philips Medical Systems

Enclosure: Collimator Label

Checklist

Is my Philips X-ray system affected by the 3 degree PBL operation and does it need to be modified?

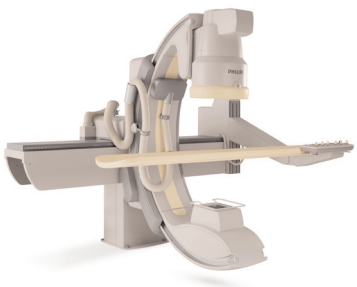
Some of the below listed general X-ray systems do not automatically collimate over the full ±3 degree range for PBL as specified in the FDA X-ray Performance Standard. The potentially affected systems are BuckyDiagnost, DigitalDiagnost, EasyDiagnost, EasyDiagnost Eleva, OmniDiagnost Eleva and MultiDiagnost Eleva systems manufactured from 1996 through September 2005 and which allow radiography with automatic collimation on radiographic cassettes. Since many users do not exactly know what type of system they have, this checklist is intended to help identifying affected and not affected systems.

BuckyDiagnost

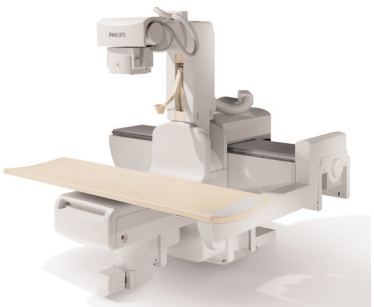
BuckyDiagnost

DigitalDiagnost

MultiDiagnost Eleva



OmniDiagnost Eleva



EasyDiagnost / EasyDiagnost Eleva

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Is my system affected?

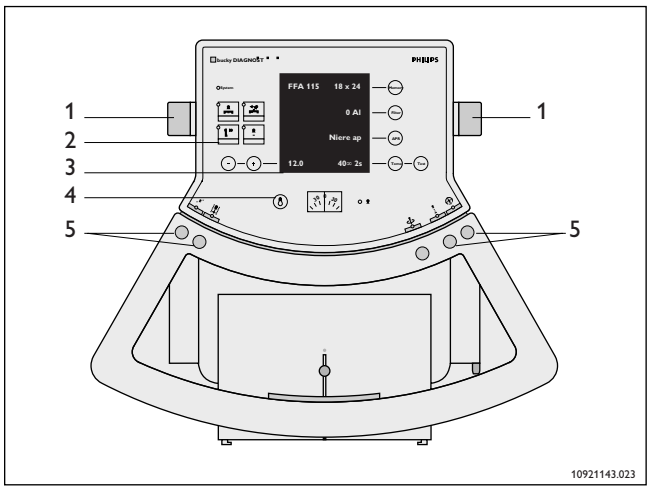
Accurately answer the questions below. If any of the first 5 questions can clearly be answered by NO, then your system is not affected and you might directly go down to Section "What action should I take?".

Question 1

Does the system have an X-ray source assembly (tube handgrip) that looks as any of the two versions shown below?

Note:
The handgrip color may be pink or light yellow. Most characteristic is the illuminated blue/green 4-line display area in the center.

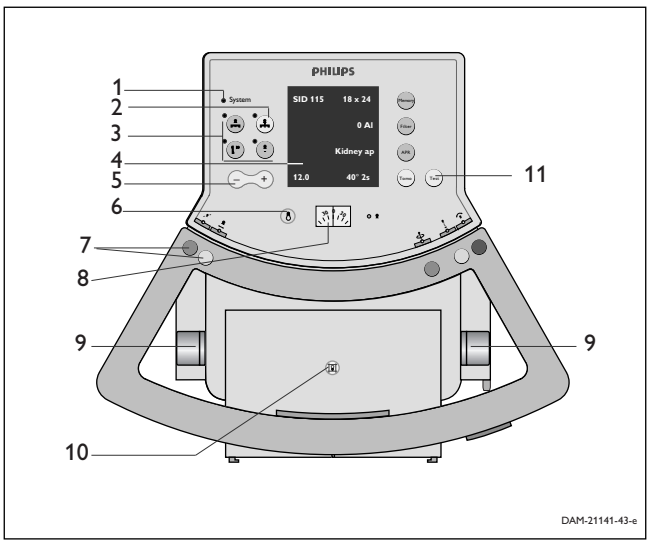
Version 1



Legend	Functions
1	Collimation
2	Selection of auxiliaries
3	Display
4	Light field-indicator and light pointer ON
5	Movements

Version 2

Legend	Functions
1	Indication: System ready for exposure
2	Tomography on/off
3	Selection of auxiliaries
4	Display
5	Set tomographic layer height
6	Light field-indicator ON and light pointer ON
7	Movements
8	Tube angle indication
9	Collimation
10	Light field-indicator ON
11	Show reason for “Not ready for exposure”



Check here, if you could identify such X-ray tube control grip in your system:

YES _ **NO** _

*If the answer is **Yes**, then also answer the next question,*
*if **No**, your system is not affected and you should proceed*
with Section “What action should I take“ further below.

Is my system affected?

Question 2

Is the X-ray tube assembly with this handgrip mounted to an independent ceiling suspension or floor stand?

Background:
Systems where the X-ray tube assembly is or can be mechanically connected to a stand are not affected (like e.g. in the DuoDiagnost). PBL requirements are not applicable for spot-film devices.

Check here:

YES _ **NO** _

*If the answer is **Yes**, then also answer the next question, if **No**, your system is not affected and you should proceed with Section "What action should I take" further below.*

Question 3

Does the X-ray tube assembly with this handgrip allow radiography on cassettes?

Or in other words:
Is there a table or vertical stand which includes a radiographic cassette holder and that, in combination with this tube assembly, allows for exposure on cassettes inside the cassette holder.

Background:
PBL requirements only apply for radiographic exposure on cassettes. This can be film cassettes and cassettes for computed radiography (like e.g. PCR).
Exposure on free cassettes is not relevant.

Check here:

YES _ **NO** _

*If the answer is **Yes**, then also answer the next question, if **No**, your system is not affected and you should proceed with Section "What action should I take" further below.*

Question 4

For radiography on cassettes, does the system support automatic collimation?

Background:
Automatic collimation means that X-ray field size is automatically adjusted and restricted to the size of the cassette. Manual collimation systems are not affected.

To check for this:
- Select a cassette auxiliary (table or wallstand, if there is both, any can be used)
- Center X-ray tube assembly on the corresponding cassette holder
- Make sure tube and receptor are both straight (table horizontal and tube pointing exactly downwards, wallstand exactly vertical and tube pointing exactly horizontal)
- Correct SID etc. until system would allow for exposure
- Check if system indicates automatic mode by displaying the SID and the cassette size in the control handle display
- In automatic mode, upon a cassette change the X-ray field size would adapt to the new cassette size, as can be seen by using the light indicator

If the system never gets into such automatic mode, check NO.

Check here:

YES _ **NO** _

*If the answer is **Yes**, then also answer the next question, if **No**, your system is not affected and you should proceed with Section "What action should I take" further below.*

Question 5

Has the system been manufactured before or in September 2005?

Background:
Systems produced afterwards are not affected by the problem.

Check the date-of-manufacture labels at table, wallstand, X-ray tube assembly handgrip and X-ray generator. It is pretty normal that these are not exactly the same.
Note that one or more components may have been exchanged later and the manufacture date for that component might be later than that for the whole system. If in question, check your system installation files.

Check here:

YES _ **NO** _

*If the answer is **Yes** (and was yes also for the other questions), your system **is affected**.*
*If the answer is **No**, your system **is not affected**. Proceed with Section "What action should I take" further below.*

What action should I take?

If your system **is not affected** and you have **not been notified** by a Philips letter on the FCO, then there is no need to do anything on your behalf.

If your system **is affected** and you **have been notified** by the FCO letter, then you should proceed as indicated in the letter (attach the label provided with the letter, and notify Philips upon X-ray tube exchange for scheduling the installation of the modification).

If you determine your system **is not affected** but you **have received** an FCO notification, please call Philips customer service at the phone number below. This will ensure that Philips deletes the corresponding entry in the FCO database and you will not be bothered by any further enquiries. Philips is required to keep track on all FCOs until resolved.

If your system **is affected** and you have **not been notified** for any reasons, then you should call Philips customer service at the number below and have your system added to the FCO list. A Philips service engineer will follow-up on your call.

FCO contact phone:

1-800-722-9377
hit menu 5 then menu 2,
then ask for RTAC (GXR tier 2)

Please have your site ID # ready when calling.

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